TANGSHAN ZHONGHONG PULIN FOOD PRODUCTS CO.,LTD.
LUANNAN,TANGSHAN CITY,HEBEI PROVINCE,CHINA
Tel: 86-315-4168379 Fax: 86-315-4168700

K022091

510 (k) SUMMARY

1) Submitter's name and address:

Baldur Systems Corporation

33235 Transit Avenue

Union City,CA 94587

DEC 3 0 2002

Telephone and Fax numbers of submitter:

Tel:510-477-9194

Fax:510-477-9634

Contact person: David Hu,Ph.d.,president

Date summary prepared: April 30,2002

2) Common name: Exam gloves

Classification name: Patient examination glove

3) Legally marketed device:

Class I vinyl patient examination gloves

80LYZ,powder-free,that meets all the requirements

of ASTM D 5250-00.

4) Description of the device:

Class I vinyl patient examination gloves

80LYZ,powder-free,that meets all the requirements

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5) Intended use of device:

A patient examination glove is a disposable Device,intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6a)Technological characteristics compared to ASTM standard D 5250 – 00:

Dimension and tolerance (S-2,AQL 4.0)

	S	M	L	XL	Tolerance	
Width	85	95	105	115	±5	(ASTM D 5250)
	85	95	105	115	±3	(ZHONGHONG)
Length	230	230	230	230	min	(ASTM D 5250)
	230	230	230	230	min	(ZHONGHONG)

Biocompatability data are conducted on the polymer coated vinyl gloves.

Physical requirements

Before and after accelerated aging 70±2 ℃ for 72±2 hours,according to D573.(Inspection level S-2,AQL 4.0)

Tensile strength (Mpa,min): 9.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

Tangshan Zhonghong Pulin Food Products Company Limited
C/O Dr. David Hu
HTI Trading Group
33235 Transit Avenue
Union City, California 94587

Re: K022091
Trade/Device Name: Vinyl Examination Gloves, Powder-Free
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: November 8, 2002
Received: December 9, 2002

Dear Dr. Hu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022091

Device Name: Vinyl Exam Gloves, Powder-free

Indications For Use:

A Vinyl patient examination glove is a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022091

Prescription Use___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1